

PEDIATRIC INVESTIGATION PLAN

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A. INTRODUCTION Full title of the trial Enter the full title of the trial Protocol code Enter the protocol code, if any (A unique identifier assigned to the trial protocol by the sponsor.) Phase If the trial is a trial of a medicinal product for human use, please specify its phase/type – Phase I – Phase II – Phase III – Adaptive design – Phase I/II – Adaptive design – Phase II/III – Adaptive design – Phase I/III – Low-risk scientific study – Bioavailability/Bioequivalence study Volunteer group Describe the volunteer group planned to be included in the trial; Specify the applicable types among those below, or a group other than these – Healthy volunteers – Patients – Male – Female – Adults – Children – Vulnerable populations (explain) – Persons unable to give consent personally (explain) Medical condition or disease under investigation Enter the name of the disease or medical condition that is the focus of the clinical trial. Scientifically recognized disease classifications (such as SNOMED, ICD and MeSH) are used, without abbreviation. In trials conducted in healthy volunteers, the intended indication for the product under development must be specified. Investigational product / method Please specify the name or code of the investigational product/method Specify the manufacturing site and facility information of the investigational product

* Competent Authority: International Council for Harmonisation (ICH) founding member authorities (US Food and Drug Administration (US FDA), European Medicines Agency (EMA), Japan Pharmaceuticals and Medical Devices Agency (PMDA)) or standing member authorities (Swiss National Medicines Authority (Swissmedic) and Canadian National Medicines Authority (Health Canada)), the Australian National Medicines Authority (TGA) or the UK National Medicines Authority (MHRA)

B. INVESTIGATIONAL PRODUCT General information on the investigational product Active substance name: Strength: Route of administration: Pharmaceutical form: Detailed information on the determination of the dose administered in the pediatric population: Risk classification of the investigational product: Important risks must be provided Identified risks must be provided Potential risks must be provided Pharmacokinetic/pharmacodynamic properties of the investigational product in the pediatric population Considering that the drug will exhibit pharmacokinetic differences in children due to reasons such as age, body weight, and level of development, the effects of these differences on potential safety and efficacy risks must be specified Assessment of clinical study data obtained with the investigational product Taking into account the limitations in the safety database (e.g., related to the size of the study population and the inclusion and exclusion criteria of the study), the effects of these limitations on the safety profile of the investigational product must be explained Information must be provided on the populations likely to be exposed to the investigational product during its intended or expected use in medical practice. Risk management plan; A risk management plan prepared to address all risks must be submitted Within the plan, risks must be well defined, the adequacy of the activities targeting the risks must be assessed, and the need for additional safety studies must be discussed If the investigational product is licensed in our country and/or by competent authorities

Information on the authority granting the license: The SmPC/PIL must be appended to the pediatric investigation plan

C. TRIAL DESIGN Summary information on other clinical trials conducted with the investigational product Summary information on safety and efficacy, obtained from data of other clinical trials conducted with the investigational product, supporting its use in the pediatric population must be provided The assessment of the relationship between the data obtained from other clinical trials conducted with the investigational product and the potential risks associated with its use in the pediatric population must be provided in this section Trial Design Risks that may

arise in the trial design must be defined and measures addressing these risks must be explained Where necessary, a plan must be submitted aimed at reducing the risk of administration and dosing errors D. VOLUNTEER When selecting the relevant volunteer group, it must be explained which scientific data were taken into consideration. The risks that may arise in the relevant volunteer group and the measures to be taken must be explained The relevant section must also include the long-term effects of drug treatment in children, as well as its effects on growth and development and on the maturation of organ-system function